

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service on the date shown below with sufficient postage as First Class Mail, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

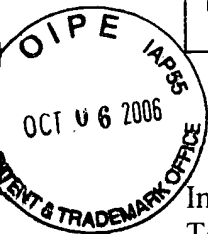
Dated: October 4, 2006

Signature:

Marian Christopher
Marian Christopher

Patent

Docket No. 220022001610



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Tom F. LUE et al.

Serial No.: 10/806,515

Filing Date: March 22, 2004

For: METHODS AND COMPOSITIONS FOR
PREVENTING AND TREATING MALE
ERECTILE DYSFUNCTION AND
FEMALE SEXUAL AROUSAL
DISORDER

Examiner: C. Qian

Group Art Unit: 1636

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97 & 1.98

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO/SB/08a/b. Copies of the documents are also submitted herewith. The Examiner is requested to make these documents of record.

This Information Disclosure Statement is submitted:

- ☐ With the application; accordingly, no fee or separate requirements are required.
- ☐ Before the mailing of a first Office Action after the filing of a Request for Continued Examination under § 1.114. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
- ☒ Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
- ☐ After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
 - ☐ A fee is required. A check in the amount of __ is enclosed.
 - ☐ A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above; accordingly; no fee is believed to be due.
- ☐ After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a check in the amount of __ is enclosed.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a Fee Transmittal form (PTO/SB/17 is attached to this submission in duplicate.)

Applicants would appreciate the Examiner initialing and returning the Form PTO/SB/08a/b, indicating that the information has been considered and made of record herein.


The information contained in this Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist;

(iii) the information, protocols, results and the like reported by third parties are accurate or enabling;
or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal form is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief (such as payment of a fee under 37 C.F.R. § 1.17 (p)) is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petition and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing 220022001610.

Dated: October 4, 2006

Respectfully submitted,

B. 

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ALTERNATIVE TO PTO/SB/08a/b (07-05)

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|---|---|----|---|--------------------------|----------------|
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | | | | Complete if Known | |
| | | | | Application Number | 10/806,515 |
| | | | | Filing Date | March 22, 2004 |
| | | | | First Named Inventor | Tom F. LUE |
| | | | | Art Unit | 1636 |
| | | | | Examiner Name | C. Qian |
| Sheet | 1 | of | 1 | Attorney Docket Number | 220022001610 |

| U.S. PATENT DOCUMENTS | | | | | |
|-----------------------|-----------------------|---|--------------------------------|--|---|
| Examiner Initials* | Cite No. ¹ | Document Number Number-Kind Code ² (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
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| FOREIGN PATENT DOCUMENTS | | | | | |
|--------------------------|-----------------------|--|--------------------------------|--|---|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear T ⁶ |
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*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|-----------------------|---|----------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| | 1. | "Cialis Filed in European Union for Once-a-Day Dosing for Erectile Dysfunction," Business Wire via NewsEdge Corp. (June 7, 2006) | |
| | 2. | "Erectile dysfunction is reversed by angiogenic gene therapy in hypercholesterolemia models," Angiogenesis Weekly via NewsEdge Corp. (June 9, 2006) | |
| | 3. | "Erectile dysfunction models benefit from intracavernosal basic fibroblast growth factor," Angiogenesis Weekly via NewsEdge Corp. (May 5, 2006) | |
| | 4. | "Research from the United States in diabetes provides new insights," Diabetes Week via NewsEdge Corp. (May 8, 2006) | |
| | 5. | BASSON et al., Journal of Sex & Marital Therapy (2001) 27:83-94 | |
| | 6. | MUSICKI et al., Mol. Pharmacol. (2005) 68:226-232 | |
| | 7. | BAKIRCIOGLU, J. Urol. (2001) 165:2103-2109 | |
| | 8. | HANAHAN, Science (1997) 277:48-50 | |
| | 9. | LEE et al., J. Urol. (2002) 167:761-767 | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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| Examiner Signature | | Date Considered | |
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